

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 16707

Simply stated, drugs are scheduled according to their abuse potential and currently accepted medical use, somewhat in the following manner:

Schedule I : No accepted medical use in the United States; high abuse potential

Schedule II : Currently accepted medical use; high abuse potential with severe psychic or physical dependence liability

Schedule III: Abuse potential less than those in Schedules I and II

Schedule IV : Abuse potential less than Schedule III

Schedule V : Abuse potential less than Schedule IV

The regulatory requirements are established based on these same schedules. Regulatory requirements include, but are not limited to, aspects of registration, recordkeeping, distribution restrictions, dispensing limits and manufacturing quotas.

There was an ongoing debate between 1956, when the issue of control was first raised, and 1977, when propoxyphene was placed into Schedule IV of the CSA, regarding whether this drug posed a public health hazard, the kind and magnitude of which warranted greater controls on its manufacture and distribution. In these debates, the issue of severity of abuse potential and addiction liability of propoxyphene compared to morphine-like drugs was always paramount. The 1957 findings of Drs. Fraser and Isbell